Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL QUALITY MEASURES CLEARINGHOUSE

General

Title

Oncology: percentage of female patients aged 18 years and older with Stage I (T1b) through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.

Source(s)

eCQI Resource Center. Breast cancer: hormonal therapy for Stage I (T1b)-IIIC estrogen receptor/progesterone receptor (ER/PR) positive breast cancer. [internet]. Washington (DC): U.S. Department of Health and Human Services; 2017 May 5 [5].

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Process

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the percentage of female patients aged 18 years and older with Stage I (T1b) through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period.

Rationale

Despite evidence suggesting the role of adjuvant endocrine therapy in lowering the risk of tumor recurrence, many female patients who should be receiving this therapy are not.

This measure assesses whether patients with a certain stage of breast cancer [I (T1b) through IIIC] and estrogen receptor (ER) or progesterone receptor (PR) positive (ER/PR+) are currently receiving the therapy.

There are allowable medical, patient, and system reasons to document instances in which a woman with Stage I (T1b) through IIIC, ER/PR+ may not be a candidate for the therapy.

Clinical Recommendation Statement

- Women diagnosed with hormone receptor-positive breast cancer who are pre- or perimenopausal should be offered adjuvant endocrine therapy with:
  - Tamoxifen for an initial duration of 5 years.
  - After 5 years, women should receive additional therapy based on menopausal status.
    - If women are pre- or perimenopausal, or if menopausal status is unknown or cannot be determined, they should be offered continued tamoxifen for a total duration of 10 years.
    - If women have become definitively postmenopausal, they should be offered continued tamoxifen for a total duration of 10 years or switching to up to 5 years of an aromatase inhibitor (AI), for a total duration of up to 10 years of adjuvant endocrine therapy.
- Women diagnosed with hormone receptor-positive breast cancer who are postmenopausal should be offered adjuvant endocrine therapy with one of the following options:
  - Tamoxifen for a duration of 10 years Or
  - An AI for a duration of 5 years. There are insufficient data currently to recommend an AI for a duration of greater than 5 years. Or
  - Tamoxifen for an initial duration of 5 years, then switching to an AI for up to 5 years, for a total duration of up to 10 years of adjuvant endocrine therapy. Or
  - Tamoxifen for a duration of 2 to 3 years and switching to an AI for up to 5 years, for a total duration of up to 7 to 8 years of adjuvant endocrine therapy.
- Women who are postmenopausal and are intolerant of either tamoxifen or an AI should be offered the alternative type of adjuvant endocrine therapy.
  - If women have received an AI but discontinued treatment at less than 5 years, they may be offered tamoxifen for a total of 5 years.
  - If women have received tamoxifen for 2 to 3 years, they should be offered switching to an AI for up to 5 years, for a total duration of up to 7 to 8 years of adjuvant endocrine therapy.
- Women who have received 5 years of tamoxifen as adjuvant endocrine therapy should be offered additional adjuvant endocrine treatment.
  - If women are postmenopausal, they should be offered continued tamoxifen for a total duration of 10 years or switching to up to 5 years AI, for a total duration of up to 10 years of adjuvant endocrine therapy.
  - If women are pre- or perimenopausal, or menopausal status cannot be ascertained, they should be offered 5 additional years of tamoxifen, for a total duration of 10 years of adjuvant endocrine therapy (Burstein et al., 2014).

Patients with invasive breast cancers that are ER- or PR-positive should be considered for adjuvant endocrine therapy regardless of patient age, lymph node status, or whether adjuvant chemotherapy is to be administered (National Comprehensive Cancer Network [NCCN], 2015).

The most firmly established adjuvant endocrine therapy is tamoxifen for both premenopausal and postmenopausal women. In women with ER-positive breast cancer, adjuvant tamoxifen decreases the annual odds of recurrence by 39% and the annual odds of death by 31% irrespective of the use of chemotherapy, patient age, menopausal status, or axillary lymph node (ALN) status. In patients receiving both tamoxifen and chemotherapy, chemotherapy should be given first, followed by sequential tamoxifen. Prospective, randomized trials have demonstrated that 5 years of tamoxifen is more effective than 1 to 2 years of tamoxifen (NCCN, 2015).

Patients with lymph node involvement or with tumors greater than 1 cm in diameter are appropriate candidates for adjuvant systemic therapy. For women with lymph node-negative, hormone receptor-negative tumors greater than 1 cm in diameter, chemotherapy is recommended. For those with lymph node-negative, hormone receptor-positive breast cancer tumors greater than 0.5 cm, the panel recommends endocrine therapy with the consideration of chemotherapy (NCCN, 2015).

Evidence for Rationale

Burstein HJ, Temin S, Anderson H, Buchholz TA, Davidson NE, Gelmon KE, Giordano SH, Hudis CA, Rowden D, Solky AJ, Stearns V, Winer EP, Griggs JJ. Adjuvant endocrine therapy for women with hormone receptor-positive breast cancer: American Society of Clinical Oncology clinical practice guideline focused update. J Clin Oncol. 2014 Jul 20;32(21):2255-69. [40 references] PubMed

eCQI Resource Center. Breast cancer: hormonal therapy for Stage I (T1b)-IIIC estrogen receptor/progesterone receptor (ER/PR) positive breast cancer. [internet]. Washington (DC): U.S. Department of Health and Human Services; 2017 May 5 [5].

National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: breast cancer. Version 3. Fort Washington (PA): National Comprehensive Cancer Network (NCCN); 2015.

Primary Health Components

Breast cancer; estrogen receptor (ER); progesterone receptor (PR); tamoxifen; aromatase inhibitor (AI) therapy

Denominator Description

All female patients aged 18 years and older with a diagnosis of breast cancer with Stage I (T1b) through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer (see the related "Denominator Inclusions/Exclusions" field)

Numerator Description

Patients who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period (see the related "Numerator Inclusions/Exclusions" field)

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

Additional Information Supporting Need for the Measure

Unspecified

Extent of Measure Testing

The American Medical Association (AMA)-convened Physician Consortium for Performance Improvement (PCPI) collaborated on a measure testing project in 2011 with American Society of Clinical Oncology (ASCO) and American Society for Radiation Oncology (ASTRO), to ensure the *Breast Cancer: Hormonal Therapy for Stage IC-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer* measure was reliable and evaluated for accuracy of the measure numerator, denominator and exception case identification. The testing project was conducted utilizing chart data. Inter-rater reliability was tested. Five sites participated in the testing of the measures. Two sites were in urban settings, two sites

were in suburban settings, and one had multiple practice sites in urban, rural and suburban settings. Site A was a hospital-based practice with 21 physicians. Site B was a physician-owned private practice with four physicians. Site C was a physician-owned private practice with 41 physicians. Site D was an academic practice with nine physicians. Site E was an academic practice with 14 physicians.

Reliability Testing

The purpose of reliability testing was to evaluate whether the measure definitions and specifications, as prepared by the PCPI, yield stable, consistent measures. Data abstracted from chart records were used to calculate inter-rater reliability for the measures.

Reliability Testing Results

There were 156 observations from five sites used for the denominator analysis. The kappa statistic value was found to be non-calculable resulting from the inability to divide-by-zero in the statistic formula when only one response was used.

Of the 156 observations that were initially selected, 156 observations met the criteria for inclusion in the numerator analysis. The kappa statistic value was found to be non-calculable resulting from the inability to divide-by-zero in the statistic formula when only one response was used.

Reliability: N, % Agreement, Kappa (95% Confidence Interval)
Denominator: 156, 100.00%, Non-Calculable (Non-Calculable, Non-Calculable)*
Numerator: 156, 100.00%, Non-Calculable (Non-Calculable, Non-Calculable)*
Exceptions: 156, 100.00%, Non-Calculable (Non-Calculable, Non-Calculable)*

This measure demonstrates perfect reliability, as shown in results from the above analysis.

*Cannot calculate kappa statistics when only one response (Yes/Yes) was used, as this causes a divide-by-zero error in the statistic formula.

Evidence for Extent of Measure Testing

American Medical Association-convened Physician Consortium for Performance ImprovementÂ® (PCPIÂ®), American Society for Therapeutic Radiology and Oncology (ASTRO), American Society of Clinical Oncology (ASCO). Oncology performance measurement sets. Chicago (IL): American Medical Association (AMA); 2015 Sep. 36 p. [5 references]

National Guideline Clearinghouse Link

(1) American Society of Clinical Oncology clinical practice guideline: update on adjuvant endocrine therapy for women with hormone receptor–positive breast cancer. (2) Adjuvant endocrine therapy for women with hormone receptor–positive breast cancer: American Society of Clinical Oncology clinical practice guideline focused update. (3) Adjuvant endocrine therapy for women with hormone receptor–positive breast cancer: American Society of Clinical Oncology clinical practice guideline update on ovarian suppression.

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Ambulatory/Office-based Care

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

Statement of Acceptable Minimum Sample Size

Unspecified

Target Population Age

Age greater than or equal to 18 years

Target Population Gender

Female (only)

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Data Collection for the Measure

Case Finding Period

The 12-month reporting period (January 1 through December 31)

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Clinical Condition

Encounter

Patient/Individual (Consumer) Characteristic

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions
All female patients aged 18 years and older with a diagnosis of breast cancer with stage I (T1b) through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer

Note:

> Date of breast cancer diagnosis is defined as date of pathologic diagnosis.
> Refer to the original measure documentation for data criteria and associated value sets.

Exclusions
None

Exceptions

> Documentation of medical reason(s) for not prescribing tamoxifen or aromatase inhibitor (AI) (e.g., patient's disease has progressed to metastatic, patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is receiving radiation or chemotherapy, patient's diagnosis date is within 120 days of the end of the 12-month reporting period, other medical reason)
> Documentation of patient reason(s) for not prescribing tamoxifen or AI (e.g., patient refusal, other patient reasons)
> Documentation of system reason(s) for not prescribing tamoxifen or AI (e.g., patient is currently

enrolled in a clinical trial, other system reasons)

Note: The denominator exception "Clinical Trial Participant" data element should be specific to breast cancer.

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions
Patients who were prescribed* tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period

Note: Refer to the original measure documentation for data criteria and associated value sets.

**Prescribed*: May include prescription given to the patient for tamoxifen or AI at one or more visits in the 12-month period OR patient already taking tamoxifen or AI as documented in the current medication list.

Exclusions
None

Numerator Search Strategy

Fixed time period or point in time

Data Source

Electronic health/medical record

Type of Health State

Does not apply to this measure

Instruments Used and/or Associated with the Measure

Unspecified

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a higher score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Identifying Information

Original Title

Breast cancer: hormonal therapy for stage I (T1b)-IIIC estrogen receptor/progesterone receptor (ER/PR) positive breast cancer.

Measure Collection Name

AMA/PCPI Oncology Performance Measurement Set

Submitter

PCPI Foundation - Clinical Specialty Collaboration

Developer

American Medical Association - Medical Specialty Society

American Society for Radiation Oncology - Medical Specialty Society

American Society of Clinical Oncology - Medical Specialty Society

Funding Source(s)

Unspecified

Composition of the Group that Developed the Measure

Unspecified

Financial Disclosures/Other Potential Conflicts of Interest

Conflicts, if any, are disclosed in accordance with the Physician Consortium for Performance Improvement® conflict of interest policy.

Endorser

National Quality Forum - None

NQF Number

not defined yet

Date of Endorsement

2017 Mar 28

Measure Initiative(s)

Physician Quality Reporting System

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2017 May

Measure Maintenance

Annual

Date of Next Anticipated Revision

Unspecified

Measure Status

This is the current release of the measure.

This measure updates a previous version: American Medical Association-convened Physician Consortium for Performance Improvement® (PCPI®), American Society for Therapeutic Radiology and Oncology (ASTRO), American Society of Clinical Oncology (ASCO). Oncology performance measurement sets. Chicago (IL): American Medical Association (AMA); 2015 Sep. 36 p. [5 references]

Measure Availability

Source available from the eCQI Resource Center Web site . Additional information available from the PCPI Web site .

For more information, contact the PCPI at 330 N. Wabash Avenue Suite 39300, Chicago, IL 60611; Phone: 312-757-7274; E-mail: PCPImeasures@thepcpi.org.

NQMC Status

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For more information, contact the PCPI at 330 N. Wabash Avenue Suite 39300, Chicago, IL 60611; Phone: 312-757-7274; E-mail: PCPImeasures@thepcpi.org.

Production

Source(s)

eCQI Resource Center. Breast cancer: hormonal therapy for Stage I (T1b)-IIIC estrogen receptor/progesterone receptor (ER/PR) positive breast cancer. [internet]. Washington (DC): U.S. Department of Health and Human Services; 2017 May 5 [5].

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